IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

(Filed: September 12, 2007)

DO NOT PUBLISH

STEPHEN KAY and LEE ANN KAY, as parents of their son, MACKLIN KAY,	)	
Petitioners,	)	
v.	)	No. 05-0562V
	)	Mercury Toxicity; Decision on
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	the Record; Dismissal
Respondent.	)	

DECISION[1]

Petitioners, Stephen Kay and Lee Ann Kay (Mr. and Ms. Kay or the Kays), as parents of their son, Macklin Kay (Macklin), seek compensation under the National Vaccine Injury Compensation Program (Program).[2] The Kays allege that Macklin exhibits "symptoms of mercury toxicity." Amended Petition for Vaccine Compensation (Am. Pet.), filed May 31, 2006, at 1. The Kays relate Macklin's condition to "thimerosal containing vaccines (*i.e.*[,] DTaP, Hep B and Hib vaccines)" that Macklin received between July 2001 and January 2003. *Id.*

[1] As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" will be available to the public. *Id.*

[2] The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

THE LEGAL STANDARD

The Kays pursue their claim upon an actual causation theory. The United States Court of Appeals for the Federal Circuit (Federal Circuit) endorses the Restatement (Second) of Torts as a "uniform approach" to resolving actual causation issues in Program cases. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1351 (Fed. Cir. 1999). Thus, to prevail, the Kays must demonstrate by the preponderance of the evidence that (1) "but for" the administration of thimerosal-containing vaccines, Macklin would not have been injured, and (2) thimerosal-containing vaccines were "a 'substantial factor' in bringing about" Macklin's injury. *Id.* at 1352, citing Restatement (Second) of Torts § 431. The preponderance of the evidence standard requires a special master to believe that the existence of a fact is more likely than not. *See In re Winship,* 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring) (quoting F. JAMES, CIVIL PROCEDURE 250-51 (1965)). Mere conjecture or speculation will not meet the preponderance of evidence standard. *See Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612, 624 (1995), *aff'd*, 73 F.3d 381 (1995).

The simple temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove actual causation. *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148-50 (Fed. Cir. 1992). Rather, long-standing, well-established Federal Circuit precedent instructs that the Kays establish a *prima facie* actual causation case by adducing "preponderant evidence" of: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also Capizzano v. Secretary of HHS*, 440 F.3d 1317, 1324 (Fed. Cir. 2006); *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994), citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993); *Grant*, 956 F.2d at 1148. The "*prima facie* case" is "a party's production of enough evidence to allow the fact-finder to infer the fact at issue and rule in the party's favor." BLACK'S LAW DICTIONARY 1228 (8th ed. 2004).

Congress prohibited special masters from awarding compensation "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a). Numerous cases construe § 300aa-13(a). The cases reason uniformly that "special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone." *Raley v. Secretary of HHS*, No. 91-0732V, 1998 WL 681467, at *9 (Fed. Cl. Spec. Mstr. Aug. 31, 1998); *see also Camery v. Secretary of HHS*, 42 Fed. Cl. 381, 389 (1998).

PROCEDURAL/FACTUAL BACKGROUND

The special master directed the factual and medical development of the case. At the outset, the special master required the parties to identify the thimerosal content in each vaccine that Macklin received. *See, e.g.*, *Kay v. Secretary of HHS*, No. 05-0562V, Order of the Special Master (Fed. Cl. Spec. Mstr. Feb. 8, 2006); *Kay v. Secretary of HHS*, No. 05-0562V, Order of the Special Master

(Fed. Cl. Spec. Mstr. Sept. 21, 2006). The parties confirm that six vaccines–three Hepatitis B vaccines and three hemophilus influenzae type-B (Hib) vaccines–that Macklin received between July 2001 and May 2002 contained no thimerosal. *See, e.g.*, Joint Status Report, filed January 19, 2007, at 2. The parties confirm that three diphtheria-tetanus-acellular pertussis (DTaP) vaccines that Macklin received between July 2001 and November 2001 contained only trace amounts of thimerosal. *See, e.g.*, Notice of Filing, filed June 12, 2007; Petitioners' Status Report, filed July 6, 2007. Indeed, respondent identifies the thimerosal content of each DTaP vaccine that Macklin received between July 2001 and November 2001 as "less than 1 nanogram of mercury (1ng = 1/1,000,000,000 g = .000000001 g.)" Notice of Filing, filed June 12, 2007, at 1.[3] The parties cannot confirm the thimerosal content of a DTaP vaccine that Macklin received on January 11, 2003. *See, e.g.*, Notice of Filing, filed June 12, 2007; Petitioners' Status Report, filed July 6, 2007. Relying upon "an excerpt from the 2001 Institute of Medicine Immunization Safety Review - Measles-Mumps-Rubella Vaccine and Autism," *see* Respondent's exhibit (R. ex.) A, respondent contends that the DTaP vaccine that Macklin received on January 11, 2003, "more likely than not, did not contain any thimerosal." Notice of Filing, filed June 12, 2007, at 1. The Kays believe that "there is a possibility that" the DTaP vaccine that Macklin received on January 11, 2003, "could also potentially have contained a 'trace' amount of thimerosal." Petitioners' Status Report, filed July 6, 2007, at 2-3.

Then, the special master required the Kays to adduce a medical expert's opinion supporting their Amended Petition. *See, e.g.*, *Kay v. Secretary of HHS*, No. 05-0562V, Order (Fed. Cl. Spec. Mstr. April 5, 2007). Appreciating the parties' conflict regarding the number of DTaP vaccines containing thimerosal that Macklin received, and the parties' conflict regarding the trace amount of thimerosal in each DTaP vaccine that Macklin received, the special master allowed the Kays' medical expert to "assume that Macklin's four DTaP vaccines contained trace amounts of thimerosal," adopting the FDA definition of "trace." *Kay v. Secretary of HHS*, No. 05-0562V, Order at 3 (Fed. Cl. Spec. Mstr. April 5, 2007). The special master provided: "The medical expert must explain thoroughly a proposition that trace amounts of thimerosal in Macklin's four DTaP vaccinations administered between July 2001 and January 2003 caused Macklin's condition." *Id.* The special master commanded the Kays to file their medical expert's opinion by September 5, 2007. *See Kay v. Secretary of HHS*, No. 05-0562V, Order (Fed. Cl. Spec. Mstr. May 15, 2007).

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[3] Based upon information published by the Food and Drug Administration (FDA), the Kays define the term "'trace'" as "'1 microgram of mercury per dose *or less*.'" Petitioners' Status Report, filed July 6, 2007, at 2 (emphasis added). Respondent's assertion that each DTaP vaccine that Macklin received between July 2001 and November 2001 contained "less than 1 nanogram of mercury," Notice of Filing, filed June12, 2007, at 1, is consistent certainly with the Kays' general position that each DTaP vaccine that Macklin received between July 2001 and November 2001 contained trace amounts of thimerosal, *see* Petitioners' Status Report, filed July 6, 2007, at 2, as one nanogram is less than one microgram.

DISCUSSION

The Kays have not proffered a medical expert's opinion supporting their Amended Petition. Instead, the Kays move for a ruling on the record. *See* Petitioners' Motion for a Ruling on the Record (Motion), filed September 6, 2007. They maintain that based upon his review of the "exhibits in this case," the special master "may now resolve the issue of whether the vaccinations (*i[.]e[.]*, DtaP, hepatitis b, Hib) [Macklin] received, more likely than not, caused him to suffer mercury toxicity." Motion at 2.

The special master has canvassed thoroughly the record. He determines that Macklin's medical records alone do not reflect an independent basis for him to find more likely than not that Macklin sustained "mercury toxicity" from "thimerosal-containing vaccines." Am. Pet. at 1. As a consequence, the Kays require unquestionably a medical expert's opinion to establish their claim. *See* § 300aa-13(a).

Yet, the Kays must concede that they have not advanced a medical expert's opinion attributing Macklin's condition to "mercury toxicity" from vaccination. As a consequence, the special master determines that the Kays have not established in the least a *prima facie* actual causation claim. *See* § 300aa-13(a)(1)(A). Therefore, in *granting* the Kays' Motion, the special master rules that the Kays are not entitled to Program compensation.

In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

s/John F. Edwards
John F. Edwards
Special Master